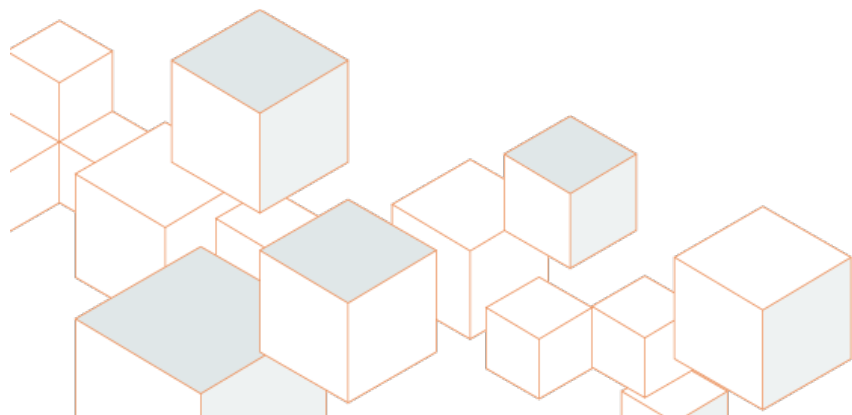


NTP Public Listening Session, November 29, 2011

# COMMENTS ON RoC REVIEW PROCESS

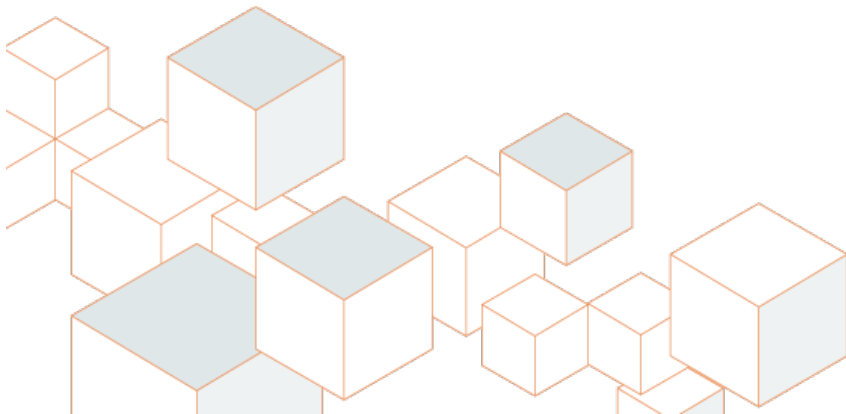
STEVE RISOTTO



il

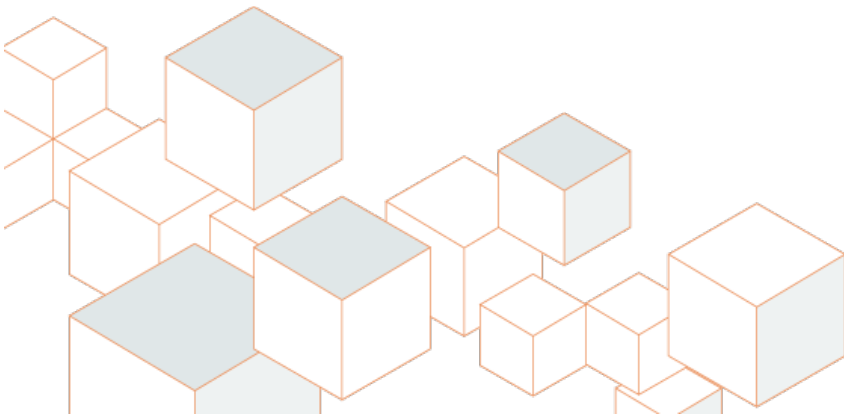
# Clarification of Listing Criteria

- **“Known” and “Reasonably anticipated” carcinogens**
  - Clarify what is meant by sufficient and limited human evidence?
  - Criteria must include more than a consideration of chance, bias, or confounding factors
  - Criteria should also include evaluation of the number and quality of studies
- **Exposure consideration**
  - Clarify what is a “significant number” of persons?
  - Specifically address the “nature” of exposure (e.g., endogenous production of formaldehyde)



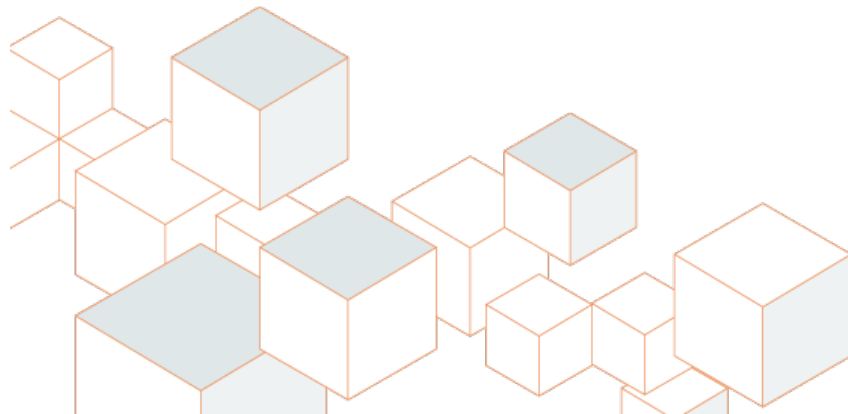
# Science vs Policy Issues

- **Consideration of all data**
  - Monographs should include negative studies and alternative interpretations
  - NTP should assess data quality of available studies
- **Weight of evidence (WoE) criteria for listing**
  - NTP must develop transparent criteria for how data will be considered
    - Criteria should be subject to public review
    - Once developed, criteria must be applied consistently
- **Listing recommendations**
  - NTP should summarize scientific controversy for peer reviewers and BSC
  - NTP should present evidence for/against listing
  - BSC should vote on listing recommendation



# Review Process

- **Selection of substances**
  - Should be subject to public & interagency review
  - Should be critically evaluated by BSC
- **Draft monograph**
  - Should be subject to public & interagency review
  - NTP should seek external scientific input from recognized experts
- **Revised draft monograph**
  - Should be subject to independent peer review - using NAS panel selection process
  - NTP should ensure appropriate level & breadth of expertise
  - Panel should receive a summary of the main points of controversy
  - The Panel's listing recommendation must be based on objective and transparent WoE criteria



# Review Process (cont.)

- **BSC Review**
  - NTP should provide a summary of main points of controversy
  - BSC should vote on listing recommendation
- **Transparency**
  - Each step of review process should be subject to public comment
  - Comments from other agencies should be made available to the public
  - NTP should develop responses to public comments
  - NTP should provide peer review panel and BSC with summary of the main points of controversy

